IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Subhashis Banerjee et al.

Serial No.: 10/622205

Filed: July 18, 2003

For: TREATMENT OF SKIN AND NAIL DISORDERS USING TNFα INHIBITORS

Attorney Docket No.: BPI-195

MS Non-Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Group Art Unit: 1641

Examiner: Not Yet Assigned

,

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Non-Fee Amendment Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date set forth below.

Date of Signature and of Mail Deposit

By:

Cristin E. Howley

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB-08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

Cristin E. Howley, Ph.D. Registration No. 55,281

Agent for Applicant

28 State Street Boston, MA 02109 (617) 227-7400

Date: April 15, 2004

GAD/EAH/CEH/alf Enclosures

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sub	stitute for form 1449A/I	B/PTO			Complete if Known	_
				Application Number	10/622205	~
II.	IFORMATION	ON DIS	SCLOSURE	Filing Date	July 18, 2003	
S	TATEMEN ⁻	T BY A	PPLICANT	First Named Inventor	Subhashis Banerjee	
	STATEMENT BY APPLICAN (Use as many sheets as necessary)		Art Unit	1641		
	(Use as many	sheets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	BPI-195	

	U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
	A1	6,090,382	07/18/2000	Salfeld et al.					
	A2	6,258,562 B1	07/10/2001	Salfeld et al.					
	A3	6,509,015 B1	01/21/2003	Salfeld et al.					

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ ⁶			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A4	Asadullah et al. "A high prevalence of cytomegalovirus antigenaemia in patients with moderate to severe chronic plaque psoriasis: an association with systemic tumour necrosis factor α overexpression." Br. J. Dermatol. 1999 Jul;141(1):94-102	
	A 5	Chaudhari et al. "Efficacy and safety of infliximab monotherapy for plaque-type psoriasis: a randomised trial." Lancet. 2001 Jun 9;357(9271):1842-7	
	A6	Davison et al. "Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy." Br. J. Dermatol. 2002 Oct;147(4):831-2	
	A7	Elewski "Infliximab for the treatment of severe pustular psoriasis." J. Am. Acad. Dermatol. 2002 Nov;47(5):796-7	
	A8	Iyer et al. "Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy." Br. J. Dermatol. 2002 Jan;146(1):118-21	
	A9	Kamarashev et al. "Generalised pustular psoriasis induced by cyclosporin a withdrawal responding to the tumour necrosis factor alpha inhibitor etanercept." <i>Dermatology</i> . 2002;205(2):213-6	
	A10	Kirby et al. "Successful treatment of severe recalcitrant psoriasis with combination infliximab and methotrexate." Clin. Exp. Dermatol. 2001 Jan;26(1):27-9	
	A11	Mackiewicz <i>et al.</i> "Dual effects of caspase-1, interleukin-1β, tumour necrosis factor-α and nerve growth factor receptor in inflammatory myopathies." <i>Clin. Exp. Rheumatol.</i> 2003 Jan-Feb;21(1):41-8	
	A12	Mang et al. "Response of severe psoriasis to infliximab." Dermatology. 2002;204(2):156-7	
	A13	Mease et al. "Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomised trial." Lancet. 2000 Jul 29;356(9227):385-90	
Examiner Signature		Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Complete if Known Substitute for form 1449A/B/PTO Application Number 10/622205 INFORMATION DISCLOSURE July 18, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Subhashis Banerjee Art Unit 1641 (Use as many sheets as necessary) Examiner Name Not Yet Assigned Sheet 2 3 Attorney Docket Number **BPI-195** of

	U.S. PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear					

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Initials	No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	Moretti et al. "Vitiligo and epidermal microenvironment: possible involvement of keratinocyte-derived cytokines." Arch. Dermatol. 2002 Feb;138(2):273-4	
	B2	Moretti et al. "New insights into the pathogenesis of vitiligo: imbalance of epidermal cytokines at sites of lesions." Pigment Cell Res. 2002 Apr;15(2):87-92	
·	ВЗ	Murota H et al. "Disruption of tumor necrosis factor receptor p55 impairs collagen turnover in experimentally induced sclerodermic skin fibroblasts." <i>Arthritis Rheum.</i> 2003 Apr;48(4):1117-25	
	B4	Newland et al. "Rapid response to infliximab in severe pustular psoriasis, von Zumbusch type." Int. J. Dermatol. 2002 Jul;41(7):449-52	
ŧ	B5	O'Quinn et al. "The effectiveness of tumor necrosis factor α antibody (infliximab) in treating recalcitrant psoriasis: A report of 2 cases." Arch. Dermatol. 2002 May;138(5):644-8	
	B6	Reuss-Borst et al. "Sweet's syndrome associated with myelodysplasia: possible role of cytokines in the pathogenesis of the disease." Br. J. Haematol. 1993 Jun;84(2):356-8	
	B7	Russell-Jones et al. "High-dose interferon and the U.K. guidelines for cutaneous melanoma." Br. J. Dermatol. 2002 Oct;147(4):832-4	
	B8	Schopf et al. "Treatment of psoriasis with the chimeric monoclonal antibody against tumor necrosis factor α, infliximab." J. Am. Acad. Dermatol. 2002 Jun;46(6):886-91	
	B9	Takematsu et al. "Absence of tumor necrosis factor-α in suction blister fluids and stratum corneum from patients with psoriasis." Arch. Dermatol. Res. 1989;281(6):398-400	
	B10	Tutuncu Z et al. "Anti-TNF therapy for other inflammatory conditions." Clin. Exp. Rheumatol. 2002 Nov-Dec;20(6 Suppl 28):S146-51	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

Application Number 10/622205

INFORMATION DISCLOSURE Filing Date July 18, 2003

				First Named Inventor	Subhashis Banerjee
•				Art Unit	1641
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	BPI-195

	U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵			
	C1	WO 02/100330 A2	12/19/2002	Abbott Laboratories					

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	ļ					
	ļ					
Examiner Signature		Date Considered				

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.